

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application Of: )  
)  
Jayanta ROY-CHOWDHURY ) Group Art Unit: 1644  
)  
Application Number: 09/171,909 ) Examiner: Ronald B. SCHWADRON  
)  
Filed: May 09, 2001 ) Confirmation No.: 8638  
)  
For: NOVEL PROCESSES IMPLEMENTING SELECTIVE  
IMMUNE DOWN REGULATION (SIDR)

**INFORMATION DISCLOSURE STATEMENT**

**Mail Stop Amendment**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

The PTO did not receive the following  
listed items(s) NPLs

Sir:

In accordance with 37 C.F.R. §§ 1.97 and 1.98, and in compliance with the duty of disclosure set forth in 37 C.F.R. § 1.56, Applicants submit attached Form PTO/SB/08A (modified) for consideration and request the references cited therein be made of record by the U.S. Patent and Trademark Office ("USPTO") in the above-captioned application.

Documents Nos. 2-6 and 9-63 on Form PTO/SB/08A have been submitted or cited by the Examiner in the parent application, U.S. Patent Application No. 09/447,704, filed November 23, 1999. Therefore, copies of the references have not been included.

In considering the cited references, it may be noted by the Examiner that certain of the references may contain markings, underlinings, and/or other notations. These markings, underlinings, and/or other notations are not to be construed as drawing the Examiner's attention either to selected parts or away from other parts of the cited references. Any such markings were either present on the copies of the cited references obtained by the associated individuals, or were made thereon during the study of the references by the associated individuals.

Additionally, Applicants wish to inform the Examiner of the existence of the following co-pending U.S. patent applications:

U.S. Application No. 09/356,294, filed July 16, 1999

U.S. Application No. 09/447,704, filed November 23, 1999

U.S. Application No. 10/377,603, filed March 4, 2003

U.S. Application No. 10/377,628, filed March 4, 2003

Applicants respectfully point out that the submission of the listed references in this Information Disclosure Statement is not an admission that they are prior art or that they are material to patentability of any claims of the application. Also, the submission of this Information Disclosure Statement is not an indication that a search has been made by Applicants.

Consideration of the foregoing plus the prompt return of a copy of the enclosed Form PTO/SB/08A with the Examiner's initials in the left column in accordance with M.P.E.P. § 609 are respectfully requested.

In accordance with 37 C.F.R. § 1.97(b), this Information Disclosure Statement is believed to be submitted prior to issuance of a first Office Action on the merits. Therefore, it is respectfully submitted that no fee is required for consideration of this Information Disclosure Statement. However, in the event any fee is deemed necessary, the Commissioner is authorized to charge the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

HUNTON & WILLIAMS

Dated: 6/3/05

By: 

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Registration No. 31,196

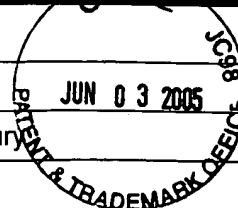
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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT***(use as many sheets as necessary)*

Application Number	09/171,909
Filing Date	05/09/2001
First Named Inventor	Roy-Chowdhury
Art Unit	1644
Examiner Name	Ronald B. Schwadron



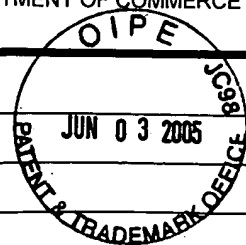
Sheet	1	of	5	Attorney Docket Number	59046.000033
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**U.S. PATENT DOCUMENTS**

*Examiner Initials	Cite No.	DOCUMENT NUMBER Number - Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	US- 5,849,285	12-15-1998	Selawry	
	2.	US- 5,872,154	02-16-1999	Wilson et al.	
	3.	US- 5,861,290	01-19-1999	Goldsmith et al.	
	4.	US- 5,935,575	08-10-1999	Lenardo et al.	
	5.	US- 6,358,509	03-19-2002	Ramanathan et al.	
	6.	US- 5,424,066	06-13-1995	Allen	

**OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS**

*Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	TRANSLATION	
			YES	NO
	7.	McMenamin et al., "Regulation of IgE Responses to Inhaled Antigen in Mice by Antigen-Specific $\gamma\delta$ T Cells," <u>Science</u> , 265:1869-1871 (1994)	<input type="checkbox"/>	<input type="checkbox"/>
	8.	Pearson et al., "Effect of anti-CD4 Monoclonal Antibody Dosage When Combined With Donor Antigen for the Induction of Transplantation Tolerance," <u>Transplantation Proceedings</u> , 23(1):565-566 (1991)	<input type="checkbox"/>	<input type="checkbox"/>
	9.	Ali et al., "The use of DNA viruses as vectors for gene therapy," <u>Gene Therapy</u> , 1:367-384 (1994)	<input type="checkbox"/>	<input type="checkbox"/>
	10.	Benjamini, E. and Leskowitz, S. (Eds.), "Transplantation Immunology," <u>Immunology: A Short Course</u> , Ch.19, 347-367 (Wiley-Liss, Inc. 2nd ed. 1991)	<input type="checkbox"/>	<input type="checkbox"/>
	11.	Cantor, H.M. and Dumont, A.E., "Hepatic Suppression of Sensitization to Antigen Absorbed into the Portal System," <u>Nature</u> , 215:744-745 (1967)	<input type="checkbox"/>	<input type="checkbox"/>
	12.	Clare-Salzler et al., "Prevention of Diabetes in Nonobese Diabetic Mice by Dendritic Cell Transfer," <u>J. Clin. Invest.</u> , 90:741-748 (1992)	<input type="checkbox"/>	<input type="checkbox"/>
	13.	Dai et al., "Cellular and humoral immune responses to adenoviral vectors containing factor IX gene: Tolerization of factor IX and vector antigens allows for long-term expression," <u>Proc. Natl. Acad. Sci. USA</u> , 92:1401-1405 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	14.	Engelhardt et al., "Ablation of E2A in recombinant adenoviruses improves transgene persistence and decreases inflammatory response in mouse liver," <u>Proc. Natl. Acad. Sci. USA</u> , 91:6196-6200 (1994)	<input type="checkbox"/>	<input type="checkbox"/>



Substitute for form 1449A/PTO				Application Number	09/356,294
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				Filing Date	7/16/1999
				First Named Inventor	Rabbani, et al.
				Art Unit	1644
				Examiner Name	Ronald B. Schwadron
Sheet	2	of	5	Attorney Docket Number	59046.000033

### OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS

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	15.	Eron et al., "Randomised trial of MNrgp120 HIV-1 vaccine in symptomless HIV-1 infection," <u>The Lancet</u> , 348:1547-1551 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
	16.	Fang et al., "Gene Therapy for Hemophilia B: Host Immunosuppression Prolongs the Therapeutic Effect of Adenovirus-Mediated Factor IX Expression," <u>Human Gene Therapy</u> , 6:1039-1044 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	17.	Fauci, A., "Host factors and the pathogenesis of HIV-induced disease," <u>Nature</u> , 384:529-534 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
	18.	Frank et al., <u>Samter's Immunologic Disease</u> , Vol. II (Little, Brown and Company 5th ed. 1995)	<input type="checkbox"/>	<input type="checkbox"/>
	19.	Fukushima et al., "Effects of Cyclosporin A on the Induction of Oral Tolerance," <u>Oral Tolerance: Mechanisms and Applications: Annals of the New York Academy of Sciences</u> , 778:376-378 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
	20.	Graham et al., <u>Methods in Molecular Biology</u> , 109-128 (The Human Press 1991)	<input type="checkbox"/>	<input type="checkbox"/>
	21.	Gregory, C. D. (Ed.), <u>Apoptosis and The Immune Response</u> (Wiley-Liss, Inc. 1995)	<input type="checkbox"/>	<input type="checkbox"/>
	22.	Guidotti et al., "High-Level Hepatitis B Virus Replication in Transgenic Mice," <u>J. Vir.</u> , 69(10):6158-6169 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	23.	Hancock et al., "Short Communication: Suppression of Insulinitis in Non-Obese Diabetic (NOD) Mice by Oral Insulin Administration Is Associated with Selective Expression of Interleukin-4 and -10, Transforming Growth Factor-beta, and Prostaglandin-E," <u>Am. J. Path.</u> , 147(5):1193-1199 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	24.	Hirahara et al., "CD4 <sup>+</sup> T Cells Anergized by High Dose Feeding Establish Oral Tolerance to Antibody Responses when Transferred in SCID and Nude Mice," <u>J. Immunol.</u> , 154:6238-6245 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	25.	Horwitz et al., "Synthesis and Assembly of Adenovirus 2: I. Polypeptide Synthesis, Assembly of Capsomeres, and Morphogenesis of the Virion," <u>Virology</u> , 39:682-694 (1969)	<input type="checkbox"/>	<input type="checkbox"/>
	26.	Horwitz, M.S., "Adenoviridae and Their Replication," <u>Virology</u> , Ch. 60, 1679-1721 (Raven Press 2nd ed. 1990)	<input type="checkbox"/>	<input type="checkbox"/>
	27.	Ilan et al., "Adoptive Transfer of Tolerance from Rats Centrally Tolerized to Adenoviral Antigens Allows Long-Term Adenovirus-Mediated Gene Therapy in Gunn Rats," <u>Hepatology: AASLD Abstracts</u> , 202A, 304 (1996)	<input type="checkbox"/>	<input type="checkbox"/>

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT***(use as many sheets as necessary)*

Application Number 09/356,294

Filing Date 7/16/1999

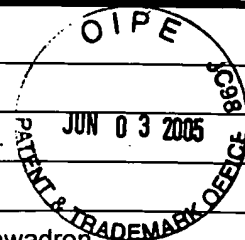
First Named Inventor Rabbani, et al.

Art Unit 1644

Examiner Name Ronald B. Schwadron

Sheet 3 of 5

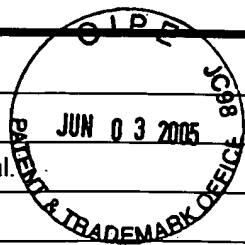
Attorney Docket Number 59046.000033

**OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS**

*Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	TRANSLATION	
	28.	Ilan et al., "Induction of Central Tolerance by Intrathymic Inoculation of Adenoviral Antigens into the Host Thymus Permits Long-term Gene Therapy in Gunn Rats," <u>J. Clin. Invest.</u> , 98(11):2640-2647 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
	29.	Ilan et al., "Transient Short Term FK-506 Treatment Permits Long Term Gene Expression Using Recombinant Adenoviruses Vectors," <u>J. Hepatol.: Postgraduate Course and Abstracts of the 31st Annual Meeting of the European Association for the Study of the Liver</u> , 23:73, WP3/019 (Supp. 1 1996)	<input type="checkbox"/>	<input type="checkbox"/>
	30.	Jaffe et al., "Adenovirus-mediated in vivo gene transfer and expression in normal rat liver," <u>Nature Genetics</u> , 1:372-378 (1992)	<input type="checkbox"/>	<input type="checkbox"/>
	31.	Kerr et al., "Apoptosis: A Basic Biological Phenomenon with Wide-Ranging Implications in Tissue Kinetics," <u>Br. J. Cancer</u> , 26:239-257 (1972)	<input type="checkbox"/>	<input type="checkbox"/>
	32.	Kroemer, G. and Martinez-A., C. (Eds.), "Current Topics in Microbiology and Immunology," <u>Apoptosis in Immunology</u> (Springer-Verlag 1995)	<input type="checkbox"/>	<input type="checkbox"/>
	33.	Kuby, J., "Cancer and the Immune System," <u>Immunology</u> , 573-596 (W.H. Freeman and Company 3rd ed. 1997)	<input type="checkbox"/>	<input type="checkbox"/>
	34.	Lederer, J. A. and A. K. Abbas, "Cytokines in Specific Immune Responses," <u>Samter's Immunologic Diseases</u> , Vol. I, Ch. 10, 129-141 (Little, Brown and Company 5th ed. 1995)	<input type="checkbox"/>	<input type="checkbox"/>
	35.	Maeda et al., "Conjugates of Anticancer Agents and Polymers: Advantages of Macromolecular Therapeutics in Vivo," <u>Bioconj. Chem.</u> , 3(5):351-362 (1992)	<input type="checkbox"/>	<input type="checkbox"/>
	36.	Maizel et al., "The Polypeptides of Adenovirus: II. Soluble Proteins, Cores, Top Components and the Structure of the Virion," <u>Virology</u> , 36:126-136 (1968)	<input type="checkbox"/>	<input type="checkbox"/>
	37.	Müller et al., "Relationship of antibodies against CD4 <sup>+</sup> T cells in HIV-infected patients to markers of activation and progression: autoantibodies are closely associated with CD4 cell depletion," <u>Immunology</u> , 79:248-254 (1993)	<input type="checkbox"/>	<input type="checkbox"/>
	38.	Peters et al., "Characterization and Tissue Specificity of a Monoclonal Antibody Against Human Uridine 5'-Diphosphate-Glucuronosyltransferase," <u>Gastroenterology</u> , 93:162-169 (1987)	<input type="checkbox"/>	<input type="checkbox"/>
	39.	Prevec et al., "Use of Human Adenovirus-based Vectors for Antigen Expression in Animals," <u>J. Gen. Virol.</u> , 70:429-434 (1989)	<input type="checkbox"/>	<input type="checkbox"/>
	40.	Rich et al. (Eds.), <u>Clinical Immunology: Principles and Practice</u> , Vol. 2 (Mosby 2nd ed. 2001)	<input type="checkbox"/>	<input type="checkbox"/>



Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				Application Number	09/356,294
				Filing Date	7/16/1999
				First Named Inventor	Rabbani, et al.
				Art. Unit	1644
				Examiner Name	Ronald B. Schwadron
Sheet	4	of	5	Attorney Docket Number	59046.000033



### OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS

*Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	TRANSLATION	
	41.	Roy-Chowdhury et al., "Bilirubin Mono- and Diglucuronide Formation by Human Liver <i>In Vitro</i> . Assay by High-Pressure Liquid Chromatography," <u>Hepatology</u> , 1(6):622-627 (1981)	<input type="checkbox"/>	<input type="checkbox"/>
	42.	Sachs et al., "Control of Programmed Cell Death in Normal and Leukemic Cells: New Implications for Therapy," <u>Blood</u> , 82(1):15-21 (1993)	<input type="checkbox"/>	<input type="checkbox"/>
	43.	Seglen, P. O., "Preparation of Isolated Rat Liver Cells," <u>Methods in Cell Biology</u> , Vol. 13, Ch. 4, 30-83 (1976)	<input type="checkbox"/>	<input type="checkbox"/>
	44.	Takahashi et al., "Acute hepatitis in rats expressing human hepatitis B virus transgenes," <u>Proc. Nat. Acad. Sci. USA</u> , 92:1470-1474 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	45.	Takahashi et al., "Long Term Correction of Bilirubin-UDP-glucuronosyltransferase Deficiency in Gunn Rats by Administration of a Recombinant Adenovirus during the Neonatal Period," <u>J. Biol. Chem.</u> 271(43):26536-26542 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
	46.	Thompson, C.B., "Apoptosis in the Pathogenesis and Treatment of Disease," <u>Science</u> , 267:1456-1462 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	47.	Thomson, A.W. (Ed.), "Molecular Medical Science Series," <u>The Molecular Biology of Immunosuppression</u> (John Wiley & Sons, Inc. 1992)	<input type="checkbox"/>	<input type="checkbox"/>
	48.	Tilney et al. (Eds.), <u>Transplantation Biology: Cellular and Molecular Aspects</u> (Lippincott-Raven Publishers 1996)	<input type="checkbox"/>	<input type="checkbox"/>
	49.	Tomei, L.D. and Cope, F.O. (Eds.), "Apoptosis II: The Molecular Basis of Cell Death," <u>Current Communications: In Cell &amp; Molecular Biology</u> , Vol. 3 (Cold Spring Harbor Laboratory Press 1991)	<input type="checkbox"/>	<input type="checkbox"/>
	50.	Tomei, L.D. and Cope, F.O. (Eds.), "Apoptosis II: The Molecular Basis of Apoptosis in Disease," <u>Current Communications: In Cell &amp; Molecular Biology</u> , Vol. 8 (Cold Spring Harbor Laboratory Press 1994)	<input type="checkbox"/>	<input type="checkbox"/>
	51.	Towbin et al., "Electrophoretic transfer of proteins from polyacrylamide gels to nitrocellulose sheets: Procedure and some applications," <u>Proc. Natl. Acad. Sci. USA</u> , 76(9):4350-4354 (1979)	<input type="checkbox"/>	<input type="checkbox"/>
	52.	Trotman et al., "Azodipyrroles of Unconjugated and Conjugated Bilirubin Using Diazotized Ethyl Anthranilate in Dimethyl Sulfoxide," <u>Analytical Biochemistry</u> , 121:175-180 (1982)	<input type="checkbox"/>	<input type="checkbox"/>
	53.	Vandenbark et al., "Definition of Encephalitogenic and Immunodominant Epitopes of Guinea Pig Myelin Basic Protein (Gp-BP) in Lewis Rats Tolerized Neonatally with Gp-BP or Gp-BP Peptides," <u>J. Immunol.</u> , 153:852-861 (1994)	<input type="checkbox"/>	<input type="checkbox"/>



Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				Application Number		09/356,294		
				Filing Date		7/16/1999		
				First Named Inventor		Rabbani, et al.		
				Art Unit		1644		
				Examiner Name		Ronald B. Schwadron		
Sheet	5	of	5	Attorney Docket Number		59046.000028		
<b>OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS</b>								
*Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published					TRANSLATION	
	54.	Walter et al., "Successful expression of human factor IX following repeat administration of an adenoviral vector in mice," <u>Proc. Natl. Acad. Sci. USA</u> , 93:3056-3061 (1996)					<input type="checkbox"/>	<input type="checkbox"/>
	55.	Weiner, H.L. and Mayer, L.F. (Eds.), "Oral Tolerance: Mechanisms and Applications," <u>Annals of the New York Academy of Sciences</u> , Vol. 778 (1996)					<input type="checkbox"/>	<input type="checkbox"/>
	56.	Weiner, H.L., "Commentary: Oral tolerance," <u>Proc. Natl. Acad. Sci. USA</u> , 91:10762-10765 (1994)					<input type="checkbox"/>	<input type="checkbox"/>
	57.	Winkelstein, A., "Immunosuppressive Therapy," <u>Basic and Clinical Immunology</u> , Ch. 61, 766-779 (Appleton & Lange 7th ed. 1991)					<input type="checkbox"/>	<input type="checkbox"/>
	58.	Wyllie et al., "Cell Death: The Significance of Apoptosis," <u>International Review of Cytology</u> , 68:251-306 (1980)					<input type="checkbox"/>	<input type="checkbox"/>
	59.	Yang et al., "Cellular and Humoral Immune Responses to Viral Antigens Create Barriers to Lung-Directed Gene Therapy with Recombinant Adenoviruses," <u>J. Virol.</u> , 69(4):2004-2015 (1995)					<input type="checkbox"/>	<input type="checkbox"/>
	60.	Yang et al., "Inactivation of <i>E2a</i> in recombinant adenoviruses improves the prospect for gene therapy in cystic fibrosis," <u>Nature Genetics</u> , 7:362-369 (1994)					<input type="checkbox"/>	<input type="checkbox"/>
	61.	Zarling et al., "HIV-infected humans, but not chimpanzees, have circulating cytotoxic T lymphocytes that lyse uninfected CD4 <sup>+</sup> Cells," <u>J. Immunol.</u> , 144(8):2992-2998 (1990)					<input type="checkbox"/>	<input type="checkbox"/>
	62.	Zhao et al., "Skin graft tolerance across a discordant xenogeneic barrier," <u>Nature Med.</u> , 2(11):1211-1216 (1996)					<input type="checkbox"/>	<input type="checkbox"/>
	63.	Ziegler, J.L. and Stites, D.P., "Hypothesis: AIDS Is an Autoimmune Disease Directed at the Immune System and Triggered by a Lymphotropic Retrovirus," <u>Clin. Immunol. Immunopathol.</u> , 41:305-313 (1986)					<input type="checkbox"/>	<input type="checkbox"/>
EXAMINER SIGNATURE				DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								